DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 99N–1852]

Draft "Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997." This draft guidance provides recommendations on procedures, content, and format for submitting a postmarketing study status report for an approved human drug or licensed biological product; timeframes for FDA's review of postmarketing studies; and information about postmarketing studies that will be available to the public. The draft guidance is intended to assist applicants in meeting the requirements of section 130 of the Food and Drug Administration Modernization Act of 1997.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by [*insert date 90 days after date of publication in the* **Federal Register**]. Submit written comments on the information collection provisions by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997" to the Drug Information Branch

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(HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling CDER at 301–827–4573 or the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION:** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Sharon T. Risso, Center for Biologics Evaluation and Research (HFM–500), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–5098; or

James L. Cobbs, Center for Drug Evaluation and Research (HFD–102), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5610.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997." Section 506B ("Reports of Postmarketing Studies") of the Federal Food, Drug, and Cosmetic Act (the act, 21 U.S.C. 356b) provides FDA

with additional authority for monitoring the progress of postmarketing studies that drug and biologics applicants have made a commitment to conduct. Postmarketing studies are those studies conducted after approval to gather information about approved drug or biologics products. Such studies are used to gather additional information about product safety, efficacy, or optimal use.

Under 506B(a) of the act, an applicant who has entered into an agreement with FDA to conduct a postmarketing study is required to provide the agency with an annual report on the status of the study until the study is completed or terminated. The annual report must address the progress of the study or the reasons for the failure of the applicant to conduct the study. Section 506B(c) of the act directs FDA to develop and publish annually in the **Federal Register** a report on the status of postmarketing studies that applicants have made a commitment to conduct and for which status reports have been submitted. In the **Federal Register** of October 30, 2000 (65 FR 64607), the agency published a final rule to implement section 506B of the act. The final rule makes several changes to the existing regulations for approved human drugs and licensed biological products.

This draft guidance, when finalized, is intended to provide information on the following: (1) Procedures concerning the submission of postmarketing study status reports; (2) the content and format of a postmarketing study status report; (3) timeframes for FDA's review of postmarketing study reports; and (4) information about postmarketing studies that will be available to the public. This draft guidance would be applicable to postmarketing studies for approved human drug products and licensed biological products that meet the definition of "drug" under the act. It would not apply to biological products that meet the definition of medical "device" under the act; or to veterinary drug products, which will be addressed separately.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document represents the agency's current thinking on the submission of postmarketing study reports for approved human drug or licensed biological products. It does not create or confer any rights for or on any person

and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations.

II. Comments

This draft document is being distributed for comment purposes only, and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by [*insert date 90 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997

This draft guidance document is intended to complement the final rule that implemented section 506B of the act by describing in greater detail the content, format, and timing requirements for the postmarketing study reports required to be submitted to FDA by section 506B. In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of the final rule to OMB for review.

In addition to the information collection provisions of the final rule submitted to OMB, this draft guidance would recommend an additional information collection. The draft guidance proposes that applicants with postmarketing study commitments submit with their annual report a redacted version of each status report that already has been formatted and completed for submission. Applicants would redact complete reports to the extent necessary to protect trade secrets or to conceal individual patient identifiers. FDA would use this redacted report for release to the public on its website and in the report on the status of postmarketing studies required under section 506B(c) of the act. FDA would accept the redacted version of the applicant's status report either in an electronic format compatible with FDA's electronic database or in hard copy.

Respondents to this information collection are applicants holding approved applications for human drugs and biological products that are required or have committed to conduct postmarketing studies.

Based on agency records, there are approximately 183 drug applicants who are required or who have committed to conduct approximately 462 postmarketing studies and approximately 33 applicants holding approved biologics license applications who are required or who have committed to conduct approximately 86 postmarketing studies. The agency assumes that all of the estimated 216 respondents would submit voluntarily approximately 548 redacted versions of their annual status reports. Based on FDA experience, the agency estimates that an applicant would expend a total of 0.5 hours preparing a redacted version of each status report that already has been formatted and completed for submission.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours
Redacted Version for Public Release	216	2.5	548	0.5	274

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with section 3507(d) of the PRA, the agency is submitting the information collection provisions of this draft guidance to OMB for review.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance document at http://www.fda.gov/cder/guidance/index.htm, or at http://www.fda.gov/cber/guidelines.htm.

Dated: March 21, 2001

March 21, 2001.

Ann M. Witt,
Acting Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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